UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/081,050	02/20/2002	David W. Osborne	359872001400	2420

21186 7590 06/12/2006

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.
P.O. BOX 2938
MINNEAPOLIS, MN 55402

EXAMINER	
CHANNAVAJJALA, LAKSHMI SARADA	
ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 06/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/081,050	OSBORNE, DAVID W.	
	Examiner	Art Unit	
	Lakshmi S. Channavajjala	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 March 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4,7-22 and 25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4,7-22 and 25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3-17-06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt of amendment, IDS, remarks all dated 3-17-06 is acknowledged.

Claims 1, 4, 7-22 and 25 are pending in this application.

The following rejections of record have been maintained:

Claim Rejections - 35 USC § 102

1. Claims 1, 4, 7, 13, 14, 20, 21 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by US 6,060,085 to Osborne or US 5,863,560 to Osborne (as evidenced by Russell, AFP, 2000).

Instant claim 1 recites a method for reducing the number of non-inflammatory acne lesions comprising the step of topically applying a composition consists essentially of dapsone. Claim 25 is directed to a method of treating non-inflammatory acne lesions comprising the step as in claim 1.

'085 and '560 discloses topical therapeutic compositions for the treatment of acne. The composition is in the form of semi-solid aqueous gel, where in the pharmaceutical is dissolved and in microparticulate form (col. 2, summary of invention-both '085 and '560). Particularly, Osborne discloses that the composition is effective with dapsone as an active agent (col. 3 of '085 and '560). Examples 2-6 in col. 9-11 (both the references) recite compositions containing dapsone, with other cosmetic additives such as methylparaben, which reads on claimed preservative. Table 1 (col. 13, both patents) recite 3% dapsone concentration. Both references disclose dapsone in a topical composition and for the same purpose i.e., treatment of acne.

Russell teaches that acne, usually diagnosed by the patient, is of three type i.e., inflammatory acne, non-inflammatory acne or a mixture of both (inflammatory and non-inflammatory) types and that the most common situation of acne is a mixture of both inflammatory and non-inflammatory (page 3, clinical manifestations & Figure 5, management of acne on page 10). While '085 and '560 does not disclose treatment of non-inflammatory acne, nothing in the above references indicate that acne (treated by Dapsone of '060 or '560) is not the commonly occurred form (as taught by Russell) and that the acne lesions are only of inflammatory type. Accordingly, both inflammatory and non-inflammatory lesions are inherent to the acne described in the teachings of '060 and '560 and therefore the claimed method of reducing the number of non-inflammatory lesions and the treatment of non-inflammatory lesions of acne is inherent to the teachings of '060 and '560.

2. Claims 8-12, 15-19 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,060,085 in view of Russell, as applied to claims1, 4, 7, 13, 14, 20, 21 and 25 above, and further in view of US 6,200,964 to Singleton et al OR over US 5,863,560 ('560) in view of Russell, as applied to claims 1, 4, 7, 13, 14, 20, 21 and 25 above, and further in view of in view of Russell and US 6,200,964 to Singleton et al.

'060 and '560 fail to teach the claimed cream, lotion, spray, suspension and ointment formulations. The above references also fail to teach 5% dapsone. Russell

suggests preparation of acne treatment formulations in the form of a gel, ointment or cream depending on the patient's skin type (page 3).

'964 teach acne treatment composition comprising salicylic acid as an active agent for the treatment and prevention of acne (col. 1). '964 teach addition of active agents such as sunscreens, antioxidants, fragrances etc., (col. 4) and teach the composition in the form of spray, cream, lotion, suspension, gel etc (col. 7, lines 20-31). '964 further teach addition of dermatologically active agent such as dapsone in the composition. It would have been obvious to one of an ordinary skill in the art at the time of the instant invention to prepare the dapsone compositions of '060 or '560 in the form of a spray, lotion or a cream or an ointment, depending the type of the skin of the patient being treated because '964 teaches acne preparations in any of the above forms and Russell suggests creams are appropriate for dry skin, gels for oily skin, lotions for any skin type and solutions fro dissolved topical antibiotics. Accordingly, it would have been within the scope of a skilled artisan to optimize the amount of dapsone (of '060 and '560) and choose the type of the formulation i.e., a gel or a lotion or a cream etc., depending on the type of skin and also depending on the solubility of the compound, with an expectation to achieve the desired effect (treatment of acne lesions- both types).

Response to Arguments

Applicant's arguments filed 3-17-06 have been fully considered but they are not persuasive.

Examiner would like to clarify that as rightly pointed out by applicants, the previous action mistakenly referred to the '085 patent as '060.

Anticipation rejection:

Claims 1, 4, 7, 13, 14, 20, 21 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by US 6,060,085 to Osborne or US 5,863,560 to Osborne (as evidenced by Russell, AFP, 2000).

Applicants argue that the fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. It is argued that the extrinsic evidence must make clear the missing descriptive matter is necessarily present in the thing described in the reference and that the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination of inherency. Applicants argue that the teaching of Russell that a mixture of both inflammatory and non-inflammatory acne lesions is the most common situation, does not lead to the conclusion that the method of using dapsone inherently reduces non-inflammatory lesions. It is argued that examiner's assumption of success in treating one form of acne must necessarily succeed in reducing the other form, simply because both forms of acne are usually present is wrong.

Applicants do not argue the teaching of Russell that acne usually occurs as a mixture of both inflammatory and non-inflammatory forms. While Russell does not state that dapsone reduces both inflammatory and non-inflammatory lesions, the teaching of Russell shows that patient populations having both inflammatory and non-inflammatory

acne exist. According to the instant disclosure as well as the cited references, dapsone is effective against inflammatory acne lesions, including those occurring in the mixed acne forms. In arguing that Russell fails to teach reduction of non-inflammatory lesions with dapsone (of '085 and '050), applicants have not provided evidence that the dapsone of '085 and '050 does not inhibit non-inflammatory lesions. Instant claims are directed to a method of reducing the number of non-inflammatory acne lesions. However, the claims do not exclude the patient population having mixed forms of acne (inflammatory as well as non-inflammatory). Therefore, dapsone inherently possess the ability to reduce the number of inflammatory as well as non-inflammatory acne lesions, when administered to patient population having both forms of acne.

Applicants argue that it is well known in the art at the time of Osborne, and is still in common practice today, that the topical antibiotics are used to reduce inflammatory but not inflammatory acne. In this regard applicants refer to the statement of Sykes that topical antibiotics have "probably" no role in treating the comedonal phase (non-inflammatory) of the disease. While Sykes teaches that topical antibiotics are useful of inflammatory phase, the statement that they have "probably" no role in treating comedonal phase does not lead to the conclusion or teach that antibiotics absolutely are not effective or do not treat non-inflammatory phase. Thus, the examiner maintains the position that the ability to inhibit comedonal phase of acne is inherent to dapsone.

Applicants argue that Osborne ('050 and '085) does not disclose non-inflammatory or comedonal acne. It is argued that even though Osborne teaches dapsone for acne, it was not actually performed at the time of filing of '085 patent

because the reference does not have any working examples. It is further stated that the first actual use of topical dapsone in treating any type of acne was in the clinical studies of the current invention, based on the approval of FDA and therefore the absence of actual use of topical dapsone for inflammatory acne by the prior art cannot attach inherency.

Applicants' arguments are not persuasive because it appears that applicants are questioning the enablement or operability of the cited Osborne patents. Applicants are reminded that every patent is presumed valid (35 U.S.C. 282), and that presumption includes the presumption of operability (Metropolitan Eng. Co. v. Coe, 78 F.2d 199, 25 USPQ 216 (D.C.Cir. 1935). An applicant need not have actually reduced the invention to practice prior to filing. Gould v. Quigg, 822 F.2d 1074, 1078, 3 USPQ 2d 1302, 1304 (Fed. Cir. 1987). Further, with respect to the argument regarding examples, the specification need not contain an example if the invention is otherwise disclosed in such manner that one skilled in the art will be able to practice it without an undue amount of experimentation. In re Borkowski, 422 F.2d 904, 908, 164 USPQ 642, 645 (CCPA 1970). Both '050 and '085 disclose the exact compositions containing dapsone, as claimed and disclose the use (applicants admitted on record) the composition for acne (col. 3, lines 12-17).

Applicants argue that because of dapsone's anti-microbial properties, one of an ordinary skill in the art would have expected topical dapsone to reduce inflammatory acne, but would not have been able to predict a non-inflammatory property. Instead, it was argued that it was applicants' disclosure that showed this surprising property.

However, "[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property, which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). In re Crish, 393 F.3d 1253, 1258, 73 USPQ2d 1364, 1368 (Fed. Cir. 2004). Admittedly, claimed dapsone is effective against inflammatory type of acne. Thus, a treatment of a mixed form of acne with dapsone should effectively reduce inflammatory lesions. With respect to the claimed non-inflammatory lesions, applicants employ the same compostion that is known for treating inflammatory acne ('085 and '560). When the claim recites using an old composition or structure and the "use" is directed to a result or property of that composition or structure, then the claim is anticipated. In re May, 574 F.2d 1082, 1090, 197 USPQ 601, 607 (CCPA 1978).

Obviousness rejection:

Claims 8-12, 15-19 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,060,085 in view of Russell OR over US 5,863,560 ('560) in view of Russell, as applied to claims1, 4, 7, 13, 14, 20, 21 and 25 above, and further in view of US 6,200,964 to Singleton et al.

With respect to the rejection of claims 8-12 and 15-19 as being unpatentable over Osborne in view of Russell and Singleton, applicants argue that examiner implicitly carried over the inherency argument. Applicants reiterate that there is no inherent ability of dapsone to reduce non-inflammatory acne, which precludes a finding of obviousness under 35 USC 103. It is argued that Russell and Singleton fail to disclose dapsone and that nothing in Osborne or the knowledge generally available in the art would lead one to treat non-inflammatory acne with dapsone. Therefore, it is argued that there is no suggestion or motivation to combine the teachings to use dapsone for non-inflammatory acne, and there would be no reasonable expectation of success in reducing non-inflammatory lesions. Applicants' arguments regarding the inherent ability of dapsone to reduce non-inflammatory acne have been adequately addresses in the previous paragraphs. Further, the motivation to prepare the composition in the form of gels, lotions etc., depending on the skin type being treated comes from the teachings of Russell and also from the teachings of Singleton. Therefore, it would have been obvious to one of an ordinary skill in the art at the time of the instant invention to prepare the dapsone compositions of '060 or '560 in the form of a spray, lotion or a cream or an ointment, depending on the type of skin and also depending on the solubility of the compound, with an expectation to achieve the desired treatment of acne lesions (both types).

Conclusion

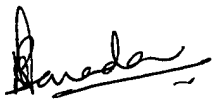
THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 9.00 AM -6.30 PM

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Lakshmi S Channavajjala
Examiner
Art Unit 1615
June 8, 2006